

REMARKS/ARGUMENTS

1. *Status of the claims*

Claims 1-5 are pending with the Amendment.

2. *Drawings*

Applicants acknowledge the draftsperson's comments attached to Paper no. 10 and will send a separate response to the draftsperson with a new drawing.

3. *Previous supplemental response*

This response reiterates arguments raised in the supplemental response filed on September 19, 2003. The supplemental response was filed in response to the Office Action mailed June 11, 2003 (paper no. 16). In response to the Office Action, Applicants filed an RCE and a request for suspension of prosecution for six months (later granted) to allow Applicants to deposit seed per the Examiner's request. The supplementary response filed on September 19, 2003 apparently crossed in the mail with the Office Action mailed September 23, 2003 (paper no. 21). During a phone conversation with the Examiner, she requested that Applicant's counsel re-file the arguments set forth in the supplemental response and further address the new issues raised in the new Office Action.

4. *Deposit*

Applicants previously requested suspension of action for this application to deposit seed under the Budapest Treaty for wheat varieties Chousen 30, Chousen 57, Turkey 116, and Kanto 79. Applicants have now deposited the seeds. As evidence of the deposit, Applicants provide herein a copy of the deposit receipt (including a translation) as well as a declaration from the inventor stating that the deposits were indeed made and that all restrictions to access will be removed when the patent application is granted.

5. *Written Description rejection*

Claims 1-5 were rejected as allegedly claiming subject matter not described in the specification in such a way as to reasonably convey that the inventors were in possession of the claimed invention. According to the Examiner, to meet the written description requirement for a genus, a representative number of species must be provided in the specification. The Examiner acknowledges that there are other ways to meet the written description requirement, but argues that they require description of the "complete structure" of the genus, which is impossible for plants. The Examiner further argues that it is not possible to describe the claimed products because there may be an infinite combination of parents that can provide progeny that can produce the claimed starch. Moreover, the Examiner argues that one of skill would not have been able to predict all of the resulting phenotypes of plants that could produce the claimed starch. Applicants respectfully traverse the rejection.

The purpose of the written description requirement, as the Examiner acknowledges, is to insure that the claimed subject matter is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the invention at the time the application was filed. As discussed in the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. Sec. 112, para. 1 'Written Description' Requirement:"

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.

The Guidelines specifically state that:

The description need only describe in detail that which is new or not conventional. This is equally true whether the claimed invention is directed to a product or a process.

See, Federal Register 1099-1111, 1106 (Vol. 66, No. 4).

The present application describes the relevant characteristics of the claimed invention, including a correlation between structure (i.e., mutation of a well-known gene) to function (high amylose content), thereby meeting the written description requirement.

The present invention relies on the very simple genetic principle that the absence of a gene encoding an active enzyme SGP-1 results in plants that have seed with a high (greater than 35%) amylose content. The claims under examination are directed to starch from such plants. Thus, all that is necessary to describe the claimed genus are the following elements: starch, wheat, SGP-1 and amylose. While it is impossible to "completely" describe a plant, it is clear that those of skill in the art would not question that "starch" or "wheat" are readily recognized in the art. Similarly, it is readily understood what amylose refers to and how to measure its quantity. *See*, paragraph spanning pages 6-7 of the specification.

Finally, the SGP-1 enzyme and methods for its detection have previously been described in the art. *See*, Yamamori and Endo, *Theor. Appl. Genet.* 93:275-281 (1996), cited on pages 3-4 of the present application. As detailed below, the application sets forth a number of ways by which plants modified to lack SGP-1 can be created. Moreover, plants lacking various SGP-1 isozymes are readily identifiable. Thus, those of skill in the art would readily understand from the specification that the inventors had possession of the full scope of the claimed invention.

The Examiner states that the relevant analysis of written description is whether the application describes the phenotype of the plant from which the starch is derived. *See*, Office Action, page 5. The Examiner states that "millions of possible phenotypes" are encompassed by the claims and so are not adequately described. *See*, page 3 of the Office Action. It is not completely clear to what the Examiner refers. It is true that the wheat plants modified to lack SGP-1 can vary greatly in their overall genotype. For example, the disease resistance of such plants could vary greatly. This fact is not relevant to the written description analysis. It is always true that "comprising" claims can include additional aspects (i.e., "millions" of different aspects). Nevertheless, if the relevant characteristics of the claimed invention are clearly described in the specification, and they are in this case, then the written description requirement has been met.

Though it does not appear to be relevant to a written description analysis, the Examiner further states that the claims may read on naturally-occurring wheat plants that contain null alleles. *See*, Office Action, page 6. As indicated in the application on the paragraph spanning pages 7-8, the term "modified" in the claim refers to plants that are artificially modified and is intended to exclude naturally occurring plants. Moreover, as recited on page 4, lines 1-4 of the present application, no wheat plant has been identified that lacks all three of SGP-A1, SGP-B1 and SGP-D1. Given the hexaploid genome of wheat, it is highly unlikely that all three genes would be homozygous null without human intervention. Applicants invite the Examiner to cite a discovery of such a naturally-occurring wheat plant. In any case, such analysis is not relevant for a written description analysis.

Accordingly, Applicants respectfully request withdrawal of the rejection.

4. *Enablement rejection*

The Examiner also rejected claims 1-4 as allegedly not enabled except for progeny of Chousen 30 or 57, Turkey 116 and Kanto 79. Applicants respectfully traverse the rejection.

As described herein, Applicants have deposited seed under the Budapest Treaty for wheat varieties Chousen 30, Chousen 57, Turkey 116, and Kanto 79. As evidence of the deposit, Applicants provide herein a copy of the deposit receipt (including a translation) as well as a declaration from the inventor stating that the deposits were indeed made and that all restrictions to access will be removed when the patent application is granted. Accordingly, Applicants request withdrawal rejection of the claims encompassing progeny of the deposited varieties.

Applicants respectfully submit that the full scope of claims 6-10 is enabled by the specification. As noted above, it appears that the Examiner believes that the full scope of the claims is not enabled by the specification **even with the requested deposit**.

Claim 1 is the broadest claim under examination and reads as follows:

Wheat starch obtained from endosperm of a seed of
wheat which is modified to lack starch granule

protein-1 (SGP-1), wherein the wheat starch has an apparent amylose content of about 35% or more.

To establish a *prima facie* case of non-enablement, the Examiner must show that undue experimentation would be required to make and use the claimed invention. As set forth in MPEP § 2164.06, even if the practice of the claimed invention requires a considerable amount of experimentation, it is not necessarily “undue” experimentation:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) (citing *In re Angstadt*, 190 USPQ 214 (CCPA 1976).

The Examiner has presented no reason to explain why undue experimentation is required to practice the claimed invention. Accordingly, the Examiner has not set forth a *prima facie* enablement rejection. Wheat starch has been generated from wheat for hundreds of years and therefore Applicants assume that the Examiner does not question that those of skill in the art know how to generate starch from wheat.

Generation of a wheat plant modified to lack SGP-1, at most, only requires routine methods well known to plant breeders of ordinary skill in the art. The Examiner has not explained why a plant breeder would have any difficulty in generating a plant lacking any gene encoding an active SGP-1 protein. The Examiner merely states that no guidance is provided regarding construction of any wheat plant having seed with an amylase content of 35 % or more. *See*, Office Action, page 4. This statement is simply not true. While the application points to specific exemplary wheat parental lines for generating such progeny, the application is generally directed to generating **any** wheat plant modified to lack SGP-1. The application teaches that any method that results in a wheat plant lacking SGP-1 can be used to make the claimed starch.

As the application teaches, wheat has a hexaploid genome and therefore has three pairs of chromosomes. *See*, page 3, line 30 of the present application. Each pair of chromosomes can carry an active SGP-1 allele. *See*, paragraph spanning pages 3-4 of the present application. The three pairs of chromosomes carry genes encoding SGP-A1, SGP-B1 and SGP-D1, respectively. SGP-A1, SGP-B1 and SGP-D1 are isozymes that are readily differentiated by

SDS electrophoresis analysis. *See*, page 3, line 30 of the present application *citing* Yamamori and Endo, *Theor. Appl. Genet.* 93:275-281 (1996) (cited in IDS).

Generation of a wheat plant modified to lack SGP-1 entails simply identifying plants that lack an active copy of at least one of SGP-A1, SGP-B1 and SGP-D1 and then crossing the plants with plants that lack an active copy of a different gene selected from SGP-A1, SGP-B1 and SGP-D1 to create a wheat plant that lacks two of the active genes. *See, e.g.*, page 8, line 16 to page 10, line 13 of the present application. A wheat plant lacking the third gene of SGP-A1, SGP-B1 and SGP-D1 is then crossed to the progeny of the first cross to produce a plant without any active gene encoding SGP-A1, SGP-B1 or SGP-D1. *See, id.*

Those of skill in the art, reading the present specification, would understand that the application describes some wheat lines that have been identified to lack at least one SGP-1 gene. *See*, page 10, lines 3-13 of the present application. In addition, it is a simple matter to screen through additional wheat lines to identify those lacking at least one SGP-1 isozyme using SDS electrophoresis. As an alternative to screening currently available wheat lines, mutagenesis can also be used to generate wheat lacking at least one SGP-1 allele. *See, e.g.*, page 11, lines 5-23 of the present application. The Examiner has presented no reason to question the availability of parental wheat lines or creation of new lines that can be used to generate a wheat plant modified to lack SGP-1.

The Examiner states that "the claims are broadly drawn to all starch having an apparent amylase content of at least 35%." *See*, Office Action, page 4. It is not clear what relevance, if any, this has to the enablement rejection. Nevertheless, a reading of claim 1 reveals that the claim requires that the wheat starch is "obtained from endosperm of a seed of a plant which is modified to lack SGP-1." Thus, the claim does not read on **all** starch having an apparent amylase content of at least 35% as the Examiner states, but instead only encompasses wheat starch from a wheat plant which has been modified to lack SGP-1. If starch can be produced from wheat plants that do not lack SGP-1, that starch would not be literally encompassed by the claims.

The Examiner has not pointed to any reason to question the arguments above. Accordingly, Applicants respectfully request withdrawal of the rejection.

Appl. No. 09/325,819
Amdt. dated December 19, 2003
Reply to Office Action of September 23, 2003

PATENT

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Matthew E. Hinsch', with a stylized, flowing script.

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